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McGhan Silicone-Filled Breast Implants

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**Adjunct Clinical Study  
Reconstruction Cohort  
Risks of First Occurrence**

## ADJUNCT STUDY - RECONSTRUCTION

Table 8: Risk of First Occurrence of Asymmetry (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk % (95% CI)	Number Affected	Number Remaining	Cumulative Risk % (95% CI)
				n	n	% (95% CI)
1 Year	195	4527	3.4% ( 2.9%, 3.8%)	220	7713	2.2% ( 2.0%, 2.5%)
3 Years	427	496	16.3% (14.4%,18.2%)	491	840	11.5% (10.2%,12.8%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 9: Risk of First Occurrence of Breast Pain (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	108	4546	1.8% ( 1.5%, 2.2%)	136	7728	1.3% ( 1.1%, 1.6%)
3 Years	207	507	7.9% ( 6.5%, 9.3%)	253	852	5.5% ( 4.6%, 6.4%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 10A: Risk of First Occurrence of Bruising (All Severity Levels)

Time	By Patient						By Implant											
	Number Affected			Number Remaining			Cumulative Risk			Number Affected			Number Remaining			Cumulative Risk		
	n	n	% (95% CI)	n	n	% (95% CI)	n	n	% (95% CI)	n	n	% (95% CI)	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	112	4521	1.8% ( 1.5%, 2.1%)	178	7681	1.7% ( 1.4%, 1.9%)	178	7681	1.7% ( 1.4%, 1.9%)	199	854	2.4% ( 2.0%, 2.9%)	199	854	2.4% ( 2.0%, 2.9%)			
3 Years	128	514	2.9% ( 2.1%, 3.6%)															

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Table 10B: Risk of First Occurrence of Bruising (>= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
1 Year	29	4557	0.5% ( 0.3%, 0.6%)	39	7738	0.4% ( 0.3%, 0.5%)
3 Years	34	523	0.7% ( 0.4%, 1.1%)	46	868	0.6% ( 0.4%, 0.8%)

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Table 11: Risk of First Occurrence of Capsular Contracture

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
			n	% (95% CI)			n	% (95% CI)
1 Year	230	4526	4.0%	( 3.5%, 4.5%)	281	7708	2.9%	( 2.6%, 3.2%)
3 Years	494	492	17.6%	(15.7%,19.4%)	600	835	12.7%	(11.5%,14.0%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 12: Risk of First Occurrence of Capsule Calcification (&gt;= Moderate Severity)

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)	Number Affected	Number Remaining	Cumulative Risk	% (95% CI)
1 Year	35	4565	0.6% ( 0.4%, 0.8%)		41	7748	0.4% ( 0.3%, 0.6%)	
3 Years	75	519	3.2% ( 2.3%, 4.2%)		92	863	2.3% ( 1.7%, 2.9%)	

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Table 13: Risk of First Occurrence of Delayed Wound Healing (&gt;= Moderate Severity)

Time	By Patient						By Implant					
	Number Affected			Number Remaining			Number Affected			Number Remaining		
	Number	Affected	Cumulative Risk	Number	Remaining	Risk	Number	Affected	Cumulative Risk	Number	Remaining	Risk
1 Year	25	4565	0.4% ( 0.3%, 0.6%)	32	7749	0.3% ( 0.2%, 0.4%)						
3 Years	31	521	0.8% ( 0.4%, 1.2%)	40	865	0.6% ( 0.4%, 0.9%)						

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Table 14A: Risk of First Occurrence of Hematoma (All Severity Levels)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	30	4558	0.5% ( 0.3%, 0.7%)	38	7739	0.4% ( 0.3%, 0.5%)
3 Years	44	521	1.5% ( 0.8%, 2.1%)	54	864	1.0% ( 0.6%, 1.4%)

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Table 14B: Risk of First Occurrence of Hematoma (&gt;= Moderate Severity)

Time	By Patient			By Implant				
	Affected	Remaining	Risk	Number		Cumulative		
				Number	Cumulative	Affected	Remaining	Risk
n	n	n	% (95% CI)	n	n	n	n	% (95% CI)
1 Year	14	4563	0.2% ( 0.1%, 0.3%)	14	7746	0.1%	( 0.1%, 0.2%)	
3 Years	18	525	0.4% ( 0.2%, 0.6%)	18	869	0.2%	( 0.1%, 0.4%)	

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## ADJUNCT STUDY - RECONSTRUCTION

Table 15A: Risk of First Occurrence of Hypertrophic Scarring (All Severity Levels)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	44	4562	0.8% ( 0.6%, 1.1%)	75	7736	0.8% ( 0.6%, 1.0%)
3 Years	170	510	6.9% ( 5.7%, 8.1%)	269	843	6.5% ( 5.6%, 7.4%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 15B: Risk of First Occurrence of Hypertrophic Scarring (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	20	4568	0.4% ( 0.2%, 0.5%)	35	7746	0.4% ( 0.3%, 0.5%)
3 Years	84	520	3.4% ( 2.6%, 4.3%)	131	861	3.1% ( 2.5%, 3.8%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 16: Risk of First Occurrence of Implant Extrusion (All Severity Levels)

Time	By Patient						By Implant		
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk		
			n	% (95% CI)			n	% (95% CI)	
1 Year	19	4564	0.3%	( 0.2%, 0.5%)	26	7746	0.3%	( 0.2%, 0.4%)	
3 Years	30	521	1.3%	( 0.6%, 2.0%)	39	864	0.9%	( 0.5%, 1.3%)	

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## ADJUNCT STUDY - RECONSTRUCTION

Table 17: Risk of First Occurrence of Implant Malposition(&gt;= Moderate Severity)

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
			n	% (95% CI)			n	% (95% CI)
1 Year	122	4548	2.1%	( 1.7%, 2.5%)	149	7728	1.5%	( 1.3%, 1.8%)
3 Years	238	516	8.5%	( 7.1%, 9.9%)	285	859	6.1%	( 5.2%, 7.1%)

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Table 18: Risk of First Occurrence of Implant Palpability

N/A: IMPLANT PALPABILITY HAS BEEN COMBINED WITH IMPLANT VISIBILITY

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Table 19: Risk of First Occurrence of Implant Rupture (All Severity Levels)

Time	By Patient						By Implant												
	Number Affected			Number Remaining			Cumulative Risk			Number Affected			Number Remaining			Cumulative Risk			
	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	% (95% CI)	% (95% CI)		
1 Year	19	4569	4569	0.3%	( 0.2%, 0.5%)		26	7749	7749	0.3%	( 0.2%, 0.4%)								
3 Years	36	521	521	1.6%	( 0.9%, 2.4%)		45	864	864	1.1%	( 0.6%, 1.6%)								

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## ADJUNCT STUDY - RECONSTRUCTION

Table 20: Risk of First Occurrence of Implant Palpability/Visibility (&gt;= Moderate Severity)

Time	By Patient						By Implant					
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk		n	n	% (95% CI)	
			n	% (95% CI)			n	% (95% CI)				
1 Year	100	4559	1.8%	( 1.5%, 2.2%)	130	7738	1.4%	( 1.2%, 1.6%)				
3 Years	286	511	11.8%	(10.2%,13.4%)	376	852	9.4%	( 8.3%,10.6%)				

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## ADJUNCT STUDY - RECONSTRUCTION

Table 21A: Risk of First Occurrence of Infection (All Severity Levels)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
				n	n	% (95% CI)
1 Year	43	4559	0.7% ( 0.5%, 0.9%)	51	7742	0.5% ( 0.4%, 0.6%)
3 Years	70	516	2.6% ( 1.7%, 3.4%)	84	659	1.8% ( 1.3%, 2.3%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 21B: Risk of First Occurrence of Infection (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
n	n	% (95% CI)	n	n	% (95% CI)	
1 Year	24	4565	0.4% ( 0.2%, 0.6%)	25	7749	0.2% ( 0.1%, 0.3%)
3 Years	34	522	1.0% ( 0.6%, 1.4%)	37	867	0.7% ( 0.4%, 0.9%)

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Table 22: Risk of First Occurrence of Irritation (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	9	4567	0.1% ( 0.1%, 0.2%)	10	7751	0.1% ( 0.0%, 0.2%)
3 Years	23	524	1.0% ( 0.5%, 1.5%)	25	868	0.6% ( 0.3%, 0.9%)

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Table 23: Risk of First Occurrence of Loss of Nipple Sensation

N/A: LOSS OF NIPPLE SENSATION HAS BEEN COMBINED WITH NIPPLE PARESTHESIA AND NIPPLE HYPERSENSITIVITY

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Table 24A: Risk of First Occurrence of Lymphadenopathy (All Severity Levels)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	7	4569	0.1% ( 0.0%, 0.2%)	12	7749	0.1% ( 0.1%, 0.2%)
3 Years	28	520	1.5% ( 0.8%, 2.2%)	38	863	1.1% ( 0.6%, 1.5%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 24B: Risk of First Occurrence of Lymphadenopathy (&gt;= Moderate Severity)

Time	By Patient			By Implant			
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk	
			% (95% CI)	n	n	% (95% CI)	
1 Year	0	4572	0.0%	--	0	7754	0.0%
3 Years	7	524	0.4% ( 0.1%, 0.8%)	7	868	0.2% ( 0.0%, 0.5%)	

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Table 25: Risk of First Occurrence of Nipple Hypersensitivity

N/A: NIPPLE HYPERSENSITIVITY HAS BEEN COMBINED WITH NIPPLE PARESTHESIA AND LOSS OF NIPPLE SENSATION

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## ADJUNCT STUDY - RECONSTRUCTION

Table 26: Risk of First Occurrence of Nipple Paresthesia/Hypersensitivity/  
Loss of Nipple Sensation (>= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n			% (95% CI)
1 Year	39	4067	0.8% ( 0.5%, 1.0%)	57	6922	0.7% ( 0.5%, 0.9%)
3 Years	153	510	7.1% ( 5.8%, 8.4%)	222	849	6.1% ( 5.1%, 7.0%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 27: Risk of First Occurrence of Pneumothorax (All Severity Levels)

Time	By Patient						By Implant					
	Number Affected		Number Remaining		Cumulative Risk		Number Affected		Number Remaining		Cumulative Risk	
	n	%	n	%	n	% (95% CI)	n	%	n	%	n	% (95% CI)
1 Year	9	4569	0.2%	( 0.1%, 0.3%)	14	7749	0.1%	( 0.1%, 0.2%)	28	864	0.7%	( 0.4%, 1.1%)
3 Years	21	521	1.0%	( 0.4%, 1.7%)								

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## ADJUNCT STUDY - RECONSTRUCTION

Table 28A: Risk of First Occurrence of Redness (All Severity Levels)

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk	n	% (95% CI)
			n			% (95% CI)		
1 Year	104	4530	1.7% ( 1.4%, 2.0%)	131	7708	1.3% ( 1.0%, 1.5%)		
3 Years	142	506	3.8% ( 2.9%, 4.7%)	177	847	2.7% ( 2.2%, 3.3%)		

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## ADJUNCT STUDY - RECONSTRUCTION

Table 28B: Risk of First Occurrence of Redness (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	42	4560	0.7% ( 0.5%, 0.9%)	46	7744	0.4% ( 0.3%, 0.6%)
3 Years	53	522	1.2% ( 0.8%, 1.7%)	58	867	0.8% ( 0.5%, 1.1%)

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Table 29A: Risk of First Occurrence of Seroma (All Severity Levels)

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
			n	% (95% CI)			n	% (95% CI)
1 Year	39	4558	0.6%	( 0.4%, 0.9%)	44	7739	0.4%	( 0.3%, 0.6%)
3 Years	55	518	1.8%	( 1.1%, 2.5%)	62	862	1.2%	( 0.8%, 1.6%)

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Table 29B: Risk of First Occurrence of Seroma (&gt;= Moderate Severity)

Time	By Patient						By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected		Number Remaining	Cumulative Risk		
				n	n		n	n	% (95% CI)
1 Year	23	4564	0.4% ( 0.2%, 0.5%)		24	7747	0.2%	( 0.1%, 0.3%)	
3 Years	28	523	0.7% ( 0.4%, 1.0%)		29	868	0.4%	( 0.2%, 0.6%)	

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Table 30: Risk of First Occurrence of Skin Hypersensitivity

N/A: SKIN HYPERSENSITIVITY HAS BEEN COMBINED WITH SKIN PARESTHESIA

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## ADJUNCT STUDY - RECONSTRUCTION

Table 31: Risk of First Occurrence of Skin Paresthesia/Hypersensitivity (&gt;= Moderate Severity)

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
			n	% (95% CI)			n	% (95% CI)
1 Year	24	4565	0.4%	( 0.3%, 0.6%)	33	7744	0.4%	( 0.2%, 0.5%)
3 Years	81	519	3.0%	( 2.2%, 3.7%)	115	862	2.6%	( 2.0%, 3.2%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 32A: Risk of First Occurrence of Skin Rash (All Severity Levels)

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
			n	% (95% CI)			n	% (95% CI)
1 Year	23	4564	0.4%	( 0.2%, 0.5%)	36	7741	0.4%	( 0.2%, 0.5%)
3 Years	42	517	1.7%	( 1.0%, 2.4%)	62	858	1.4%	( 0.9%, 1.9%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 32B: Risk of First Occurrence of Skin Rash (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	9	4569	0.1% ( 0.1%, 0.2%)	11	7750	0.1% ( 0.0%, 0.2%)
3 Years	15	522	0.6% ( 0.2%, 0.9%)	21	864	0.5% ( 0.3%, 0.8%)

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Table 33A: Risk of First Occurrence of Swelling (All Severity Levels)

Time	By Patient				By Implant			
	Number Affected		Number Remaining		Number Affected		Number Remaining	
	Cumulative Risk	% (95% CI)	Cumulative Risk	% (95% CI)	Cumulative Risk	% (95% CI)	Cumulative Risk	% (95% CI)
1 Year	207	4.48%	3.3% ( 2.9%, 3.8%)		309	7.63%	2.9%	( 2.6%, 3.2%)
3 Years	257	5.04	6.3% ( 5.2%, 7.3%)		371	8.44	5.0%	( 4.3%, 5.7%)

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Table 33B: Risk of First Occurrence of Swelling(&gt;= Moderate Severity)

Time	By Patient						By Implant		
	Affected	Number Remaining	Number Cumulative	Risk	Number Affected		Number Remaining	Cumulative Risk	
					n	n		% (95% CI)	
1 Year	92	4538	1.5% ( 1.2%, 1.8%)		122	7714	1.1%	( 0.9%, 1.4%)	
3 Years	109	518	2.3% ( 1.8%, 2.9%)		142	862	1.7%	( 1.4%, 2.1%)	

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Table 34A: Risk of First Occurrence of Tissue or Skin Necrosis (All Severity Levels)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
1 Year	29	4559	0.5% ( 0.3%, 0.7%)	37	7741	0.4% ( 0.3%, 0.5%)
3 Years	40	517	1.3% ( 0.7%, 1.9%)	51	861	0.9% ( 0.6%, 1.3%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 34B: Risk of First Occurrence of Tissue or Skin Necrosis (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	14	4567	0.2% ( 0.1%, 0.3%)	15	7751	0.1% ( 0.1%, 0.2%)
3 Years	16	522	0.3% ( 0.1%, 0.5%)	18	867	0.2% ( 0.1%, 0.3%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 35: Risk of First Occurrence of Wrinkling (&gt;= Moderate Severity)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	92	4554	1.6% ( 1.3%, 2.0%)	119	7733	1.3% ( 1.0%, 1.5%)
3 Years	251	503	9.4% ( 7.9%,10.8%)	328	841	7.3% ( 6.3%, 8.3%)

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Table 36A: Risk of First Occurrence of Other Complications (All Severity Levels)

Time	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
			n	n	n	% (95% CI)
1 Year	33	4565	0.6% ( 0.4%, 0.8%)	44	7744	0.4% ( 0.3%, 0.6%)
3 Years	76	518	3.4% ( 2.3%, 4.4%)	97	861	2.5% ( 1.9%, 3.3%)

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## ADJUNCT STUDY - RECONSTRUCTION

Table 36B: Risk of First Occurrence of Other Complications (&gt;= Moderate Severity)

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
			n	% (95% CI)			n	% (95% CI)
1 Year	15	4570	0.2%	( 0.1%, 0.4%)	19	7752	0.2%	( 0.1%, 0.3%)
3 Years	45	522	2.0%	( 1.2%, 2.7%)	57	866	1.5%	( 1.0%, 2.0%)

Attachment 16

Inamed Corporation  
PMA P020056  
McGhan Silicone-Filled Breast Implants

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